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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,128	11/27/2001	Alan N. Houghton	MSK.P-026-3	3698

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,128	HOUGHTON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *3,6-9,13-16,18 and 25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 10-12, 17 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date May 23, 2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1, 2, 4, 5, 10-12, 17 and 19-24) in the reply filed on July 26, 2004 is acknowledged. The traversal is on the ground(s) that "[r]estricting consideration to only the specific species claimed unfairly limits the ability of Applicants to claim their invention as they understand it" and the claims of Groups II, III and IV should be recombined...", see page 1 of Remarks submitted July 26, 2004. This is not found persuasive because as noted on page 4 of the election/restrictions mailed June 25, 2004 the differentiation antigens are patentably distinct and structurally different from one another and would elicit different immune responses (i.e. respond to different antibodies). Classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed proper and adhered to.

2. Claims 1-27 are pending.

Claims 3, 6-9, 13-16, 18 and 25-27, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 2, 4, 5, 10-12, 17 and 19-24 are examined on the merits to the extent that the xenogeneic differentiation antigen is a human tyrosinase.

Specification

3. The instant application properly reflects the current status of the parent application in the first line of the specification. The application 09/308,697 filed May 21, 1999 is now a U.S. Patent and the filing date of to international application number PCT/US97/22669 is not listed. Applicants are requested to review the first line of the specification and include all pertinent and proper information.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 4, 5, 10, 11 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim a method for treating melanoma in a mammalian subject comprising administering a xenogeneic differentiation antigen. It is clear from dependent claims that the xenogeneic antigen is a human tyrosinase protein with the

sequence of SEQ ID NO: 1. The written description in this instant case only sets forth Sequence ID No. 1 consisting of 6408 nucleic acid residues. Applicants' are only in possession of the human species of tyrosisnase. As the claims presently read they embrace sequences from enumerable species of animals. The written description is not commensurate in scope with the broadly claimed method using a xenogenic differentiation antigen of undefined sequences encoding it.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115). With the exception of Sequence ID No: 1 and 2 from humans, the skilled artisan cannot envision the detailed structure of the plethora of differentiation antigens and with particularity tyrosinase. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of the human differentiation antigen, tyrosinase encoded by Sequence ID No: 1. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 4, 5, 10-12, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al. (The Journal of Immunology 156: 3151-3158, May 1, 1996), and further in view of Naftzger et al. (Proc. Natl. Acad. Sci. USA 93: 14809-14814, December 1996/ IDS reference on page 2 submitted March 5, 2002). Disis teaches overcoming tolerance to self-tumor antigens is key in the generation of effective anti-tumor immunity. Disis teaches a method for overcoming self tolerance to the Her-2/neu antigen by the administration of sub-dominant epitopes of rat Her-2/neu. Disis does not teach treating melanoma in a mammalian subject comprising administering to a dog an immunologically-effective amount of human tyrosinase antigen of the same type as tyrosinase antigen expressed by melanoma cell of the dog.

However, Naftzger teaches the concept of administration of an altered source gp75 a tyrosinase-related protein either syngeneic gp75 expressed in insect cells or human gp75 elicited rejection of metastatic melanomas, see page 14809, Abstract. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to immunize dogs with the xenogeneic form of human tyrosinase. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Disis on the requirement for breaking self-tolerance to tumor antigens in order to elicit an effective anti-tumor immune response and by presenting to a host a homologous but non-identical protein. Furthermore, it would have *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the same methodology presented by

Naftzger because gp75 is closely related to tyrosinase and the outcome of the method established tumor protection. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Naftzger wherein immune responses induced with altered antigen reacted with various processed forms of native, syngeneic protein could induce tumor rejection.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 4, 5, 10-12, 17 and 19-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13 and 16-19 of copending Application No. 10/041,410 (filed January 7, 2002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the broadly claimed method of the copending application reads on the instant application's method for treating melanoma

with a human differentiation antigen, tyrosinase. Tyrosinase is one of the target differentiation antigens of copending document 10/041,410. It is reasonable to conclude that the tyrosinase of application '410 is the same as the instant application's and would have identical sequences. Furthermore, the immunologically-effective amount of xenogeneic differentiation antigen administered would be composed in a pharmaceutically acceptable form thereby reading on the copending applications claims featuring a vaccine formulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
01 November 2004